

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 480208.408D1	APPLICATION NO. 10/788,649
O I P E SEP 17 2004 P A T E N T O F F I C E I N F O R M A T I O N D I S C L O S U R E S T A T E M E N T (Use several sheets if necessary)		APPLICANTS Thomas D. Madden et al.			
		FILING DATE February 27, 2004	GROUP ART UNIT 1636		

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>lu</i>	AA	4,235,871	11/25/80	Papahadjopoulos et al.	424	19	
	AB	4,501,728	02/26/85	Geho et al.	424	38	
	AC	4,837,028	06/06/89	Allen	424	450	
	AD	5,023,087	06/11/91	Yau-Young	424	450	
	AE	5,552,156	09/03/96	Burke	424	450	
	AF	5,814,335	09/29/98	Webb et al.	424	450	
	AG	5,837,282	11/17/98	Fenske et al.	424	450	
	AH	5,976,567	11/02/99	Wheeler et al.	424	450	
	AI	6,110,491	08/29/00	Kirpotin	424	450	
<i>lu</i>	AJ	6,355,268	03/12/02	Slater et al.	424	450	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
<i>lu</i>	AK	WO 95/08986	04/06/95	WIPO		
	AL	WO 98/17256	04/30/98	WIPO		
	AM	WO 99/51202	10/14/99	WIPO		
	AN	WO 00/23052	04/27/00	WIPO		
	AO	WO 99/13816	03/25/99	WIPO		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>lu</i>	AP	Burris, H., et al., "Activity of Topotecan, a New Topoisomerase I Inhibitor, Against Human Tumor Colony-Forming Units In Vitro," <i>J. Natl. Cancer Inst.</i> 84(23):1816-1820, December 2, 1992.
<i>lu</i>	AQ	Clements, M., et al., "Antiangiogenic Potential of Camptothecin and Topotecan," <i>Cancer Chemother. Pharmacol.</i> 44:Pages 411-416, 1999.

EXAMINER	<i>lu</i>	DATE CONSIDERED
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INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANTS Thomas D. Madden et al.	
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lu	BA	60/215,556		Madden et al.			06/30/00
lu	BB	09/896,812		Madden et al.			06/29/01
lu	BC	60/264,616		Madden et al.			01/26/01

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	BD					

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

lu	BE	Corbett, T., et al., chapter 5 "In Vivo Methods for Screening and Preclinical Testing," in B. Teicher, Ed., <i>Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval</i> , Humana Press Inc., Totowa, NJ, 1997, pp.75-99.
	BF	Emerson, D., et al., "In Vivo Antitumor Activity of Two New Seven-substituted Water-soluble Camptothecin Analogues," <i>Cancer Res.</i> 55:603-609, February 1, 1995.
	BG	Erickson-Miller, C., et al., "Differential Toxicity of Camptothecin, Topotecan and 9-Aminocamptothecin to Human, Canine, and Murine Myeloid Progenitors (CFU-GM) in Vitro," <i>Cancer Chemother. Pharmacol.</i> 39:467-472, 1997.
	BH	Grochow, L., et al., "Pharmacokinetics and Pharmacodynamics of Topotecan in Patients with Advanced Cancer," <i>Drug Metab. Dispos.</i> 20(5):706-713, 1992.
	BI	Hardman, W., et al., "Efficacy of Treatment of Colon, Lung and Breast Human Carcinoma Xenografts With: Doxorubicin, Cisplatin, Irinotecan or Topotecan," <i>Anticancer Res.</i> 19:2269-2274, 1999.
	BJ	Hope, M., et al., "Generation of Multilamellar and Unilamellar Phospholipid Vesicles," <i>Chem. Phys. Lip.</i> 40:89-107, 1986.
	BK	Hsiang, Y-H., et al., "Identification of Mammalian DNA Topoisomerase I as an Intracellular Target of the Anticancer Drug Camptothecin," <i>Cancer Res.</i> 48:1722-1726, April 1988.
	BL	Kearney, A. et al., "Preformulation Studies to Aid in the Development of a Ready-to-Use Injectable Solution of the Antitumor Agent, Topotecan," <i>Int. J. Pharm.</i> 127:229-237, 1996.
	BM	Gruner, S., chapter 1 "Materials Properties of Liposomal Bilayers," in Ostro, M.J. (ed.), <i>Liposomes: From Biophysics to Therapeutics</i> , Marcel Dekker, New York, 1993, pp. 1-38.
lu	BN	Madden, T., et al. "The Accumulation of Drugs Within Large Unilamellar Vesicles Exhibiting a Proton Gradient: A Survey," <i>Chem. Phys. Lipids</i> 53:37-46, 1990.

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
	CB				YES NO

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

lu	CC	Madden, T., et al., "Encapsulation of Topotecan in Lipid-based Carrier Systems. Evaluation of Drug Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L1210 and B16 Tumors," <i>Proc. Of ASCO 17</i> , abstract #754, 1998.
	CD	Mayer, L., et al., "Characterization of Liposomal Systems Containing Doxorubicin Entrapped in Response to pH Gradients," <i>Biochim. Biophys. Acta</i> 1025:143-151, 1990.
	CE	McCabe, F., et al., "Comparative Activity of Oral and Parenteral Topotecan in Murine Tumor Models: Efficacy of Oral Topotecan," <i>Cancer Invest.</i> 12(3):308-313, 1994.
	CF	O'Leary, J., et al., "Antiangiogenic Effects of Camptothecin Analogues 9-Amino-20 (S)-Camptothecin, Topotecan, and CPT-11 Studied in the Mouse Cornea Model," <i>Clin Cancer Res.</i> 5:181-187, January 1999.
	CG	Ormrod, D. et al., "Topotecan A Review of its Efficacy in Small Cell Lung Cancer," <i>Drugs</i> 58(3):533-551, September 1999.
	CH	Plowman, J., et al., chapter 6, "Human Tumor Xenograft Models in NCI Drug Development," in B. Teicher, Ed, <i>In Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval</i> , Humana Press Inc., Totowa, NJ, 1997.
	CI	Szoka, F., et al., "Comparative Properties and Methods of Preparation of Lipid Vesicles (Liposomes)," <i>Ann. Rev. Biophys. Bioeng.</i> 9:467- 508, 1980.
	CJ	Tardi, P., et al., "Liposomal Encapsulation of Topotecan Enhances Anticancer Efficacy in Murine and Human Xenograft Models," <i>Cancer Res.</i> 60:3389-3393, July 2000.
	CK	Thompson, J., et al., "Animal Models for Studying the Action of Topoisomerase I Targeted Drugs," <i>Biochim. Biophys. Acta</i> 1400:301-319, 1998.
	CL	Wall, M., et al., "Plant Antitumor Agents. I. The Isolation and Structure of Camptothecin, a Novel Alkaloidal Leukemia and Tumor Inhibitor from Camptotheca Acuminata," <i>J. Am Chem. Soc.</i> 88:3888-3890, August 1966.
lu	CM	Waud, W., chapter 4 "Murine L1210 and P388 Leukemias," In B. Teicher, Ed, <i>Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval</i> , Humana Press Inc., Totowa, NJ, 1997.

EXAMINER	<i>kuh</i>	DATE CONSIDERED	12/04
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